Zedler, Barbara

From: Jenny Camp [Jenny.Camp@clinimetrics.com]
Sent: Wednesday, September 29, 2004 11:02 AM
To: Larson, Mary; Jan.Oey@pmusa.com; Barbara.K.Zedler@pmusa.com
Cc: jcamp@clinimetrics.com
Subject: SAE reporting

Thanks Mary. That sounds like a reasonable process!

-----Original Message-----
From: Larson, Mary [mailto:Mary.Larson@covance.com]
Sent: Wednesday, September 29, 2004 10:45 AM
To: Jenny Camp; Jan.Oey@pmusa.com; Barbara.K.Zedler@pmusa.com
Cc: Larson, Mary
Subject: RE: slides late

There were no SAEs in the TES study. Our plan was to report on Medical History as this was not an interventional study and of very short duration for the subjects.

Mary

-----Original Message-----
From: Jenny Camp [mailto:Jenny.Camp@clinimetrics.com]
Sent: Wednesday, September 29, 2004 8:31 AM
To: Jan.Oey@pmusa.com; Barbara.K.Zedler@pmusa.com; Larson, Mary
Subject: RE: slides late

Thank you Jan. I will assume we will use the same SAE process as we have in our previous Philip Morris trials.

-----Original Message-----
From: Jan.Oey@pmusa.com [mailto:Jan.Oey@pmusa.com]
Sent: Tuesday, September 28, 2004 5:19 PM
To: Barbara.K.Zedler@pmusa.com; Jenny Camp; Mary.Larson@covance.com
Subject: RE: slides late

I do not recall any SAE in the TES.

Jan

-----Original Message-----
From: Zedler, Barbara
Sent: Tuesday, September 28, 2004 5:14 PM
To: 'Jenny Camp'; Larson, Mary
Cc: Zedler, Barbara; Oey, Jan
Subject: RE: slides late

Good point re SAEs. Mary and Jan, did we have any in the TES?? I can't recall any. It's kind of a moot point, though, as this was not an interventional study, only observational.

Source: https://www.industrydocuments.ucsf.edu/docs/tjdj0001

Barb

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-----Original Message-----
From: Jenny Camp [mailto:Jenny.Camp@clinimetrics.com]
Sent: Tuesday, September 28, 2004 2:55 PM
To: Larson, Mary
Cc: Barbara.K.Zedler@pmusa.com
Subject: slides late
Importance: High

Hi Mary,

I will be able to get the TES coordinator meeting slides to you no later than tomorrow. I have been out sick with strep but I promise to get these to you tomorrow.

Question
SAE reporting - How are SAEs reported? How were they reported in your previous study?

Thanks
Jenny

Jenny Camp
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